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Hyseq Inc
670 Almanor Avenue
Sunnyvale, CA 94085

EXAMINER
SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
1634	11

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/672,221	BOYLE ET AL.	
	Examiner	Art Unit	
	Jehanne Souaya	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,11,25 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,11,25 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 September 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Currently, claims 10-11, 25 and newly added claim 31 are pending in the instant application. Claims 1-9, 12-24 and 26-30 have been canceled. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied (necessitated by amendment) or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The instant specification contains an embedded hyperlink and/or other form of browser-executable code (p. 115). The examiner has disabled the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Maintained Rejections

4. Claims 10-11, 25 and newly added claim 30 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to isolated polypeptides comprising the amino acid sequence of SEQ ID NOS 4 and 6-17. The claims further encompass isolated polypeptides that are at least 99% identical to SEQ ID NOS 4 and 6-17. The specification teaches that SEQ ID NO 4 is predicted to be encoded by the nucleic acid of SEQ ID NO 3, and that SEQ ID NO 17 is the mature form of SEQ ID NO 4. The specification teaches that SEQ ID NO 15 is a signal peptide which is located at positions 1-18 of SEQ ID NO 4 and is the extracelluar portion of SEQ ID NO 4 [see p. 117-119]. The specification further teaches that 9 Leucine Rich Repeats (LRR) were predicted to be present in SEQ ID NO 4 and correspond to SEQ ID NOS 6-14. The specification, however, does not teach the biological activity or function of SEQ ID NOS 4 or 17 or where "active domains" are located. The specification asserts that the signal peptide, SEQ ID NO 15, and the predicted transmembrane portion, SEQ ID NO 16, have use on their own, but teaches that this use (which is not disclosed in the specification) must be confirmed by expression in mammalian cells (see pp 117-118) and sequencing of the cleaved product (in the case of SEQ ID NO 15, p. 117, lines 26-27). Leucine rich repeats are generally known to be involved in protein protein interactions, however a large class of proteins exist which contain leucine rich repeats, having a wide range of functions (see Kobe and Deisenhofer, 1995 and analysis below), therefore the prediction of putative leucine rich repeats in SEQ ID NO 4 would not indicate to one of skill a specific or substantial utility for the claimed polypeptides.

The specification asserts the following uses for the claimed polypeptides: at page 7, lines 10-15, the specification teaches that the polypeptides can be used a) to generate an antibody that

specifically binds the polypeptide, b) as molecular weight markers, and c) as food supplements. The specification further asserts that the claimed polypeptides can be used as potential therapeutics in the treatment of heart failure, nerve injury, insulin and non insulin dependent diabetes, muscle disorders, tumor growth, stress syndromes, inflammation, blood clotting, immune function, and bleeding disorders. (p. 7, lines 20-29). At pages 49-50 (bridging paragraph), the specification teaches that the polypeptides can also be used in assays to determine biological activity or levels of protein in biological fluids, and also to isolate correlative receptors or ligands. The claimed polypeptides, however, are not supported by a specific asserted utility because the disclosed uses of the polypeptides are not specific and are generally applicable to any polypeptide. These are non-specific uses that are applicable to polypeptides in general and not particular or specific to the polypeptide being claimed.

Further, the claimed polypeptides are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a polypeptide can be used to obtain an antibody. The antibody could then be used in conducting research to isolate the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case, none of the antibodies that are to be produced as final products resulting from processes involving claimed polypeptides have specific and substantial utilities. The research contemplated by

applicant(s) to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context of use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility of the utility has not been assessed.

It is noted that the specification teaches that SEQ ID NO 4 has 44% similarity and 30% identity to human insulin like growth factor binding protein complex acid labile subunit (ALS), which contains leucine rich repeats. Absent factual evidence, however, a percentage sequence identity of less than 100% is not deemed reasonable to support one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of a similar known biomolecule. Kobe and Deisenhofer (1995, Current Opinion in Structural Biology, 1995, pp 409-416, referred to as "Kobe") teach that known LRR containing proteins have only two things in common: repetitive sequences and involvement in protein protein interactions (see p. 410, col 1 and 2, Fig 2 and table 1). Kobe teaches that LRR proteins take part in a wide range of processes, such as signal transduction, cell adhesion, development, DNA repair, recombination, transcription, and RNA processing, and that recently, it was discovered that some LRR containing proteins can bind non protein ligands. Table 1 illustrates the wide range of functions

of LRR containing proteins. Thus, the prediction of putative leucine rich repeats in SEQ ID NO 4 would not indicate to one of skill in the art a specific or substantial utility for the claimed polypeptides as the structural similarities of certain regions of SEQ ID NO 4 to other LRR proteins does not indicate the specific biological function or activity of the claimed polypeptides or to specific diseases that can be identified or treated with the claimed polypeptides. With regard to a use for a single leucine rich repeat, Kobe teaches that a single leucine-rich motif most probably does not fold into a defined structure and that several LRRs appear to jointly form a module and that the function of LRR domains can be modulated by changing the number of repeats with a single domain (see p. 412, col 1).

The specification also teaches that SEQ ID NO 4 also has 45 % similarity and 32% identity to human glycoprotein V protein (see p 117). Bernard-Souleir syndrome, an inherited bleeding disorder, is caused by a lack of functional GP Ib-IX-V complex. It is known for nucleic acids as well as proteins, however, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. (See Russel et al, J. Mol. Biol. Vol. 244, 1994, pp 332-350, who teaches that the results of an analysis of side chain to side chain secondary structure and accessibility between related proteins suggest that there is little in common between distantly related protein structures and that secondary structure lengths and loops in distantly related structures vary substantially- p. 345). The specification does not teach the biological function or activity of SEQ ID NOS 4 or 6-

17. Furthermore, the specification provides no specific or substantial utility as to the use of the claimed polypeptides in therapeutics for bleeding disorders, or more specifically for Bernard Souleir syndrome. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecule and therefore lacks support regarding utility. Further experimentation would be required of the skilled artisan to determine a use for the polypeptides of the claimed invention. As noted by Brenner v. Manson, 383 US 519, 535-536 (1996), "Congress intended that no patents be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use - testing... a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

Claim Rejections - 35 USC § 112

Enablement

5. Claims 10-11, 25 and newly added claim 31 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

6. The response traverses the rejection. The response asserts that the claimed polypeptides show strong homology to members of the LRR family of proteins, including ALS and glycoprotein (GP) Ib and V and that these proteins are useful in and of themselves and that as such, one of ordinary skill in the art reading Applicant's specification would clearly understand the utility of proteins homologous to ALS. This argument has been thoroughly reviewed but was found unpersuasive. Firstly, the examiner has not questioned the utility or use of either ALS, GP Ib, GP V. Secondly, the functions for ALS and (GP) Ib and V are different, as aknowledged by the specification. The specification teaches that IGFs are involved in diverse cellular processes including cell cycle progression and proliferation (p. 2) and that after birth, ALS, synthesized by the liver, sequesters most of the IGF's into ternary complexes. Regarding (GP) Ib and V, the specification teaches (p. 3) that GP V is cleaved by thrombin from the platelet surface during activation and that GP Ib, on the other hand, has been shown to bind vWF and thrombin. The specification further teaches that while GP V is shown to be required for the expression of the GP Ib-IX-V complex on the cell surface, GP Ib has been shown to bind Mac-1 on leukocytes and could promote vascular inflammation during thrombosis). Therefore, the artisan, from reading applicant's specification, would be taught that SEQ ID NO 6 has homology to two different proteins from the LRR superfamily, wherein the proteins have entirely different functions. Since the specification does not teach what the specific function or activity of SEQ ID NO 6 is, the artisan would not know which of these proteins SEQ ID NO 6 functions like. Thus, while it is

generally known that LRR proteins are involved in protein-protein interactions, different polypeptides in the LRR superfamily are involved in "interactions" with different proteins, as exemplified by the different functions of ALS, GP Ib, and GP V. The examiner does not question that SEQ ID NO 6 likely belongs to the LRR superfamily, however, only knowing that the claimed SEQ ID NO is involved in "protein-protein interactions" without knowing what specific interactions are involved, does not provide the artisan with a use for the polypeptides. To determine a use for the claimed polypeptides, the artisan would first have to determine the function and/or activity of the claimed polypeptides, which is not readily apparent merely based on the knowledge that the protein in question contains leucine rich repeats. As noted by Brenner v. Manson, 383 US 519, 535-536 (1996), "Congress intended that no patents be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use - testing... a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

The response further traverses that Kobe et al support the utility of the claimed polypeptides by acknowledging that the high conservation of residues at consensus positions throughout the LRR superfamily make it very likely that the structure of LRRs in other proteins will closely resemble that of the LRRs in ribonuclease inhibitor (RI), which binds/sequesters ribonuclease. This argument has been thoroughly reviewed but was not found persuasive. Firstly, it is noted that nowhere in this analysis does Kobe teach that the functions or ligands of such "other proteins" are the same or similar. In fact, Kobe acknowledges that despite "progress

in the past year, not enough is known structurally about the diverse protein ligands of LRR containing proteins to draw any general conclusion about possible common properties of the ligands" (see p 414, para bridging cols 1 & 2). Without knowledge of the function or ligands of specific LRR proteins, the artisan would not be able to determine what the function or activity of particular protein is based on homology data alone. This is exemplified by table 1 of Kobe which teaches a large number of proteins with leucine rich repeats which have different functions, and Kobe's comparison of the structural similarities between RI and pectate lyases which have different functions. Therefore, applicants traversal that Kobe supports the utility of the claimed polypeptides is not found persuasive. The response further traverses that given the teachings of Kobe and the similarity of the claimed polypeptides to ALS, there is sufficient teaching in the [art] to show the utility of the claimed polypeptides. This argument was thoroughly reviewed but was found unpersuasive because the artisan, upon reading the different functions of RI and ALS, would not know which of the proteins, SEQ ID NO 6 would function like.

The response asserts that the Russel et al reference cited by the examiner cannot be properly used to conclude that the sequence homology presented by Applicants means that the claimed invention is not a member of the LRR family of proteins. This argument has been thoroughly reviewed. Applicants traversal is not understood, however, because the previous office action does not question the fact that the claimed polypeptides belongs to the LRR family of proteins. Rather, the previous office action indicated that because LRRs represent a large

family of proteins with different biological functions, homology that indicates membership to such a broad class does not indicate the specific function of the claimed polypeptides.

The response asserts that although the sequences of the present invention may be considered to have a low degree of homology to a known protein family, the sequences are believed to share comparable three dimensional structure and biological functions with members of the known LRR family of proteins and cite a number of publications that applicants assert "clearly demonstrate that structure and function is preserved among proteins that are members of protein families". The response then concludes that "the reference of Yang and Konig provides extensive support for the position adopted by applicant that extent of sequence identity between the claimed sequences and the known protein sequences identified by BLAST searches is sufficient to preserve three dimensional folding among members so identified and thereby to maintain essential functional attributes common to the proteins in question". These arguments as well as the references have been thoroughly reviewed but were not found persuasive.

With regard to the reference by Strynadka and James, although the ordinary artisan might be able to determine that a protein possesses residues implicated in calcium binding, and thus conclude that the protein is a calcium binding protein, the ability of a protein to bind calcium does not provide the ordinary artisan with a "real world" use for the polypeptide because a large number of calcium binding proteins are known in the art, having different biological functions and involved in different biological mechanisms. Thus if the ordinary artisan were in possession of an uncharacterized protein which through homology analysis was found to possess residues

implicated in calcium binding, such would not be sufficient to allow the ordinary artisan to determine whether the protein in question would function like or be involved in similar biological mechanisms as troponin C, calmodulin, parvalbumin, or intestinal calcium binding protein (proteins in the alignment taught by Strynadka and James).

With regard to the Pabo et al reference, the same analysis holds true. Motifs have been taught in the art, ie homeodomains, zinc finger domains, steroid receptor domains, etc, which have similar structures, however these motifs occur in proteins with different functions. For example, the alignment regarding steroid receptor domains taught by Pabo et al include progesterone, thyroid, vitamin D, estrogen, androgen, and glucocorticoid (see p. 1075). Thus, the fact that an uncharacterized protein contains a steroid receptor domain does not provide the ordinary artisan with a "real world" use for the polypeptide, that is, does it function like progesterone? thyroid? vitamin D? estrogen?, etc.

While Yang and Honig, teach that in general, similar structures can fold without having a set of highly conserved residue clusters or a well conserved sequence profile, Yang and Honig do not teach how to determine how the structural motifs analyzed, would function to make a "real world" use apparent to the ordinary artisan. The possession of structures indicative of a serine protease in an uncharacterized protein, does not make the specific biological function or the specific biological mechanism that the protein is involved in readily apparent to the ordinary artisan. With regard to the references in general, again the previous office action did not question that the claimed polypeptides belong to the LRR family, however, inclusion in this broad family

of proteins does not indicate to the ordinary artisan how to use the claimed polypeptide. The specific mode of action or ligand interactions of the polypeptide is unknown, the possible role of the claimed polypeptide or agonists or antagonists of the claimed polypeptide in a specific disease is unknown and further experimentation is required to determine such.

Skolnick (Skolnick and Fetrow, TIBTECH, January 2000, vol. 18, pp 34-39) teaches (p. 35, "Box 1") that a common protein characteristic that makes functional analysis based only on homology especially difficult is the tendency of proteins to be multifunctional. Skolnick teaches that for example, lactate dehydrogenase binds NAD, substrate, and zinc and performs a redox reaction and that each of these occurs at different functional sites that are in close proximity and the combination of all four sites creates the fully functional proteins. Skolnick also cites RecA which contains a DNA binding domain, a multimerization domain and additional sites that bind regulatory proteins. Skolnick also teaches that the serine threonine phosphatase superfamily is a prime example of the difficulties of using standard sequence analysis to recognize the multiple functions found in single proteins. Skolnick teaches that this large protein family is divided into a number of subfamilies, all of which contain an essential phosphatase active site. He teaches that subfamilies 1, 2A and 2b exhibit 40% or more sequence identity between them, however each of these subfamilies is apparently regulated differently by the cell and observation suggest that there are different functional sites at which regulation can occur. Skolnick teaches that because the sequence identity between subfamilies is so high, standard sequence similarity

methods could easily misclassify new sequences as members of the wrong subfamily if the functional sites are not carefully considered.

With regard to applicants position that sequence identity identified in BLAST searches is sufficient to preserve three dimensional folding among members and thereby to maintain essential functional attributes common to the proteins in question, this argument has been thoroughly reviewed but was not found persuasive. Firstly, it is noted that "the essential functional attributes" of either ALS, GP Ib, or GP V are not taught in the specification. Further, Fetrow teaches (Fetrow et al., J. Mol. Biol., vol. 282, pp 703-711, 1998) that although function prediction by homology to previously characterized proteins is extremely successful and is fast, cheap and reliable, there are several problems that limit its potential utility, one of which is that sequence homology does not guarantee functional similarity (p 704, col. 1, 1st full paragraph). Fetrow teaches that "threading"(analysis using structure prediction tools) can identify topological cousins, that is , protein families such as the αβ barrels with similar structures, but dissimilar functions. Fetrow teaches using a three dimensional descriptor of the active site of a protein, termed "fuzzy functional form" (FFF) and argues that threading alone is not enough to provide the required information about function because it has been shown that pairs of proteins can have similar structures but unrelated functions (p. 706, col. 2, last para). Fetrow teaches that because such topological cousins exist, knowledge of the structure is not equivalent to identification of protein function. Again, although the alignment studies provided by applicant indicate that the claimed polypeptide contain leucine rich repeats, and that the claimed polypeptide likely belongs

to the LRR, such alignment is not sufficient to indicate to the ordinary artisan the specific function or biological activity of the claimed polypeptides, so that the ordinary artisan would know how to use the claimed invention. The art specifically teaches, that sequence alignment alone does not necessarily provide a predictable correlation between the structure and specific function of a protein. For these reasons, and the reasons made of record above, and in the previous office action, the rejection of claims 10-11, 25 and newly added claim 31 under 35 USC 101 is maintained.

Written Description

7. Claims 10-13 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 4 and 6-17 Polypeptides comprising SEQ ID NOS 4 and 17 and polypeptides consisting of the sequences of SEQ ID NOS: 6-16 meet the written description provisions of 35 USC 112, first paragraph. However, claims 10, 11, 25, are directed to polypeptides that comprise an amino acid sequence of SEQ ID NOS 6-16 and newly added claim 31 is directed to a polypeptide that comprises an amino acid sequence which is 99% identical to SEQ ID NOS 4, and 6-17. The claims encompass full length proteins belonging to the leucine rich repeat family and which contain one of SEQ ID NOS 6-16 as well as functional

fragments, mutated sequences, allelic variants, and splice variants from any species. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. The teachings of Kobe illustrate that LRR proteins are a diverse class of proteins, and that proteins from this broad genus, while containing certain structural similarities to other LRR proteins, have very different functions. Thus a single full length protein sequence (SEQ ID NOS 6 and 17) from this broad genus is not representative of the functionally different proteins from this broad class. Absent a written description disclosing a representative number of proteins of this broad class of proteins, the specification fails to show that applicant was "in possession of the claimed invention" at the time the application for patent was filed.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NOS: 4, and 6-17, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The

polypeptide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Accordingly, the specification does not provide a written description of the invention of claims 10-13 and 25.

Response to Arguments

8. The response traverses the rejection. The response asserts that in the previous office action, the examiner "noted that polypeptides comprising SEQ ID Nos 6 and 17, and SEQ ID NOS 6-16 met the written description requirement of 35 USC 112, first paragraph" and that the presently amended claims are directed to this subject matter. This argument has been thoroughly reviewed but was not found persuasive as the examiner indicated in the previous office action, that polypeptides "consisting" of the sequences of SEQ ID NOS: 6-16 met the written description

requirement of 35 USC 112, first paragraph. The examiner did not indicate that polypeptides "comprising" SEQ ID NOS: 6-16 met the written description requirement, however the claims are still drawn to such [SEQ ID NOS 6-16]. Applicants further assert that newly added claim 31 meets the written description requirements. This argument was thoroughly reviewed but was not found persuasive for the reasons made in section 7 above.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. No claims are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634
7/9/02

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600